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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,152	07/30/2001	Desmond John Best	PC10947A	2963

7590 04/23/2003

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EXAMINER
BERCH, MARK L

ART UNIT	PAPER NUMBER
1624	19

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/918,152	BEST ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 March 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *See memo*.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See memo*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-18 and 21-24*.

Claim(s) withdrawn from consideration: _____.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☒ Other: *PTO-892*

Mark L. Berch
Primary Examiner
Art Unit: 1624

DETAILED ACTION

The amendment filed 3/14/03 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search. The amendment to claim 23 has muddled the claim. Why is the Formula III material present at all? What role does the "...dotted line..." text have in defining the claim? This could be fixed by retaining the definitions for the variables and jettisoning the reference to Formula III. In addition, the "boronate reagent" in claim 11 introduces a new issue. Such a term has not been used in the claims before. It is not clear what the scope of this term is, nor have applicants indicated where in the specification there is descriptive support for it. The examiner cannot locate the term in the specification.

Even if entered, the amendment to the next to last line of claim 1 would not have solved the issue of the first rejection. Of course, one knows that a salt could be formed only if R3 is H. The problem, as indicated, is that the claim is not drawn to the manufacture of salts in the first place. It is drawn to the manufacture of II, and II is not a salt. It is an optionally protected acid. Thus, the optional step provides for the making of a product that is not permitted in the first place.

The term "suitable" is not in the specification, and it is not clear specifically what it is supposed to entail, and hence this raises a new issue as well. The rest of the traverse is unpersuasive. Applicants state, "Applicants had interpreted the Examiner's rejection of the phrase "readily removable" as based on the notion that only groups that

are readily removable would be considered in the art to be protecting groups." But that was not the examiner's point. The actual text was as follows:

What does "easily removable" mean? Where is the line between protecting groups which are easily removable and those which are not?

That is, some protecting groups are easily removable, some protecting groups are not easily removable, but it was not clear where the line was between the two. The original claim was not drawn to any protecting group, only to those which are "easily removable", which is a category of protecting groups. Thus, one of the references cited by applicants states that the acetal group is "a good protecting group for aldehydes because it is easily introduced and removed." And while it is true, as applicants state that one of ordinary skill in the art can choose a "suitable protecting group" --- one that will protect the group in question --- the original claims were drawn more narrowly, just to one which is readily removable. Please note that being difficult to remove does not mean that something is not a protecting group. Sometimes, being difficult to remove is a drawback. Thus, 5688925 at column 1, lines 20-26 states, "A further disadvantage of the method described in Swiss Patent 514,578 is that the expensive and toxic reagent benzyl chloroformate must be used for the protection whilst hydrogenation, a difficult and dangerous step to conduct on an industrial scale (especially in a plant designed for the synthesis of anti-cancer compounds) is required for removal of the protecting group." In other cases, a group difficult to remove may be preferred. Thus, 5464826 states at Column 5, lines 31-35, "The t-butyldimethylsilyl group is a special case and is preferred as the protecting group in this synthesis; it is more difficult to cleave, requiring a reagent such as a hydrohalic acid to remove it from the hydroxy groups."

The problem, however, is that there is no line between these two groups, so that one can tell which protecting groups are intended and which protecting groups are not intended. That is, the term "easily removable" is one of degree. Terms of degree are indefinite when the specification contains no "explicit guidelines" to distinguish from things which are not so, *Ex parte Oetiker*, 23 USPQ2d 1651, 1655 (1990) and Ex parte Oetiker, 23 USPQ2d 1641. See also *Ex Parte Anderson*, 21 USPQ2d 1241 at 1250, for "comparable" and "superior". Note MPEP 2173.05(b) which states, "When a term of degree is presented in a claim, first a determination is to be made as to whether the specification provides some standard for measuring that degree. If it does not, a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention. Even if the specification uses the same term of degree as in the claim, a rejection may be proper if the scope of the term is not understood when read in light of the specification ... when the scope of the claim is unclear a rejection under 35 U.S.C. 112, second paragraph is proper. See In re Wiggins, 488 F. 2d 538, 541, 179 USPQ 421, 423 (CCPA 1973)." There are no guidelines to distinguish between groups which are easily removed and which are not.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.

Mark L. Berch
Primary Examiner
Art Unit 1624

April 16, 2003